

ROLE OF TRADITIONAL MEDICINE IN PROMOTING THE WELL-BEING OF THE PEOPLE IN SOUTH ASIA

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SUMMARY

All countries in South Asia have a rich heritage of Traditional Medicine (TM). According to the World Health Organization (WHO), large segments of the population in countries of South Asia are served by practitioners of TM. If large segments of the population resort to TM for their healthcare needs, the government should evolve public health policies to ensure that the herbal remedies prescribed by the practitioners of TM or bought over the counter are safe, effective and of good quality. According to the WHO, only 25 of WHO's 191 Member States have developed public policies on TM.

The objective of this conference is to promote the continuous development of TM in the region to maximize their contribution to public health. The agenda has been structured to achieve the objective of the conference. The major thrusts of this agenda are to:

- Review the current situation in countries of the region;
- Introduce the concepts of quality, efficacy and safety of herbal and other remedies used in TM.
- Preserve the community knowledge, folk-lore and biodiversity found in abundance in countries of the region.
- Explore the possibilities of regional and sub-regional collaboration by promoting networking of practitioners of TM and health activists at the grass-roots levels.
- Examine the role of TM in achieving Health for All as outlined in Alma Ata in September 1978.

These issues will be taken up at round table discussions with a moderator and selected number of resource persons. The discussions will help the participants examine in-depth the prospects and problems facing practitioners of TM, the communities served by the practitioners, policy makers, regulators and research scientists in their efforts to make use of the full potential of TM to improve and promote the health and well-being of people in the region.

As a health activist, I look forward to the in-depth discussions on several issues related to TM enabling the participants to identify major components of a public policy on TSM. Such a policy will provide a sound basis for defining the role of TM in national healthcare delivery, ensuring that the necessary regulatory and legal mechanisms are created for promoting and maintaining good practice, that access is equitable and that the authenticity, safety, efficacy and quality of therapies are assured.

Moreover, it can help to ensure sufficient provision of financial resources for education, training and research. An increased number of national policies on TSM in the region would have the added benefit of facilitating collaborative

activities on regional issues such as development and implementation of regionally accepted norms for quality, safety and efficacy of TM, sustainable use of medicinal plants and protection and equitable knowledge of indigenous and traditional medicine.

INTRODUCTION

I am honoured to be given the opportunity to give an introduction to this conference where very knowledgeable practitioners and research workers in traditional medicine are presenting papers and taking part in round table discussions.

The objective of this conference is to promote the continuous development of traditional medicine in the region to maximize its contribution in preserving and improving public health. The agenda has been structured to achieve the objective of the conference. I see the agenda structured in two sections:

- Situation analysis and sharing of experiences and
- Action oriented round table discussions.

Situation analysis will give us a baseline from where we can take off and two important issues have been identified:

- Carrying out research to evaluate safety and efficacy of different traditional medicine therapies.
- Action plans to preserve and safeguard the bio diversity, sustainability and traditional knowledge.

I shall focus on these two action oriented round table discussions. I shall present two scenarios and wish to underscore that the two are mutually exclusive. Each one is equally important. However, I wish you to consider which is relevant to achieve the objectives of this conference.

EVALUATION OF SAFETY AND EFFICACY OF TRADITIONAL MEDICINE

I believe that this conference will focus on herbal remedies which constitute the therapeutic armamentarium of traditional systems of medicine in the region.

The World Health Organization (WHO) has defined herbal medicines as "Finished labeled medicinal products that contain ingredients from aerial or underground parts of plant parts or other plant material or combination thereof, whether in the crude state or as plant preparations.⁽¹⁾ The same WHO document adds "Medicines containing plant material combined with chemically defined active substances, including chemically defined substances and isolated constituents of plants are not considered to be herbal medicines".

It will therefore, follow that chemically defined isolated constituents of plants used

¹ World Health Organization; *WHO Technical Report Series* No 863, 1996. Annex 11. Guidelines for the Assessment of Herbal Medicines, pp 178-183.

in modern medicine are not herbal medicines, it has been estimated that these medicines derived from plants constitute about 25 percent in modern pharmacopoeia.(2)

The World Health Organization posed a question in 2002(3), whether a herbal medicine can be used clinically if no harm has been found after the use of that herbal medicine for generations and there is no documentation of such an effect. For an answer to the question, reference is made to an earlier WHO document published in 2000(4), which states "Absence of reported or documented side effect is not an absolute assurance of safety of herbal medicine. However, a full range of toxicology tests may not be necessary. Tests which examine effects that are difficult or even impossible to detect clinically should be encouraged. Suggested tests include immunotoxicity, genotoxicity, carcinogenicity and reproductive toxicity". It adds the following caveat, "only when there is no documentations of long historical use of a herbal medicine or when doubts exist about its safety, should additional tests be performed.

A rigid framework that has been prepared for modern synthetic drugs will never be possible for herbal medicines. There has to be some flexibility in toxicological requirements for herbal medicines.

Accordingly, a group of experts met in Chandigarh in India, to develop a suitable framework for carrying out toxicological studies on herbal medicines. The framework developed was broadly accepted by the Indian Council of Medical Research and the WHO. The actual tests to be carried out in the Chandigarh model are given in tables 1 & 2. The tests recommended by the WHO are given in Table 3.

WHO has called on clinical researchers to conduct clinical evaluation of traditional medicines within the specific framework of rigorous clinical pharmacological principles without ignoring or trampling on the concepts of the traditional systems of medicine.

I wish to take this opportunity to present an alternate view for evaluation of traditional medicine.

Traditional systems of medicine are a summation of several thousands of years of human experience in the selection of plants for preventive and curative healthcare.

² De Silva T, "Production of the Herbal Medicines in Developing Countries, paper presented at the International Symposium on Herbal Medicine, Honolulu, Hawaii, 1-4 June, 1997 organized by the University of San Diego in California in Collaboration with the United National Industrial Organization

³ Chandhury R R & Chandhury M R, "Standardization, preclinical toxicology and clinical evaluation of medicinal plants, including ethical in Traditional Medicine in Asia, New Delhi (2002)

⁴ General Guidelines for methodologies on research and evaluation of traditional medicine WHO, Geneva 2000. ⁵ Chaudhury R R Herbal Medicine for Human Wealth. WHO-SEARO – New Delhi, 1992

Practitioners of traditional systems of medicine argue that the efficacy of herbal remedies is due to the synergistic activity among the several ingredients of herbal mixtures. Complex mixtures of plants or herbs form the basis of traditional medicines. The mixtures are usually subject to crushing, heating, boiling, etc. It is possible that this process may change the chemical structure of the active ingredients in the plants.

Clinical pharmacologists and other scientists working on medicinal plants, on the other hand, focus all their attention on isolating and identifying biologically active ingredients in medicinal plants and herbs. When a promising new biologically active chemical ingredient is isolated, it goes through all subsequent investigations identical to those for a new synthetic chemical ingredient.

Table 1. Tests required for subacute toxicology studies

Liver function	Serum Albumin/Globulin, Total proteins Alkaline phosphatase, Bilirubin SGOT/SGPT
Renal function	Blood Urea Serum Creatinine
Heamatology	Heamoglobin RBC, WBC Total and Differential, ESR, PCV
Others	Cholesterol, Glucose

Table 2. Duration of toxicity studies

Single administration or repeated administration for less than one week	2 weeks to 1 month
Repeated administration from one week to four weeks	4 weeks to 3 months
Repeated administration between one to six months	3 to 6 months
Long-term repeated administration for more than six months	9 to 12 months

Table 3. Toxicity profile recommended by WHO for herbal medicines(10)

Acute toxicity	Tests should be performed on two species – one rodent and one non-rodent. Males and females from one species at least. Five animals per group per sex in rodents and at least two animals per sex in non-rodents. Oral route orally or route of intended administration Different dose levels
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Observation studies	Toxic, signs, reversibility of signs. Animals to be observed for 7-14 days. Autopsy of any animal which dies with histopathology of organ showing macroscopic changes at autopsy.
Long-term toxicity	Two species one rodent and one non-rodent. Both sexes to be user. Rodents — 10 male and 10 female. Non-Rodents — Both sexes to be used Rodents – 10 male and 10 female. Non – Rodents- three males and three females. Route - expected route of clinical use. Administration period will vary with expected period of clinical use. Three different dose levels administered seven days a week.
Observation studies	General signs, body weight, food and water intake - Haematological examination Renal and hepatic function tests
Other tests of appropriate period of administration recommended	E.C.G.; Visual and Auditory

Traditional healers do not accept that the efficacy is necessarily due to the active ingredients in the plant.

According to the active ingredient approach the modern clinical pharmacologists, take the knowledge from the plant but throws away the wisdom of centuries.

If there is acceptable historical evidence that traditional herbal remedies have been effective in the treatment of certain diseases, but neither their active ingredients nor the mechanisms are known, is it ethically or morally acceptable to not use that treatment? Examples of successful treatment by traditional medicines will be useful to answer these questions,

In the late 1980s children attending the Dermatology Department, Hospital for Sick Children, Great Ormond Street, London showed marked improvements in their eczema symptoms. These improvements were due to oral treatment with aqueous decoctions of a mixture of 10 Chinese medicinal herbs¹⁰. Clinical experimentation and pharmacological testing revealed that a mixture of the 10 herbs were necessary and that the efficacy could not be attributed to any single active ingredient from any one of the 10 Chinese herbs. A placebo controlled double-blind clinical trial using the 10 Chinese herbs was carried out on 47 selected children with non-exudative eczema. The conclusions of the trial were to validate the standard of current conventional clinical trials utilized in the UK that

¹⁰ Harper, J I Et al 1990, "Chinese herbs of eczema", The Lancet, 335: 795

the traditional Chinese therapy was efficacious.¹¹

If these children had to wait till the clinical pharmacologists had screened the 10 Chinese plants for active ingredients and tested them for biological activity, they would never have been given the chance of getting effective treatment with a mixture of 10 Chinese herbs.

Potential cytotoxic drugs are tested for their activity against experimental or human cancer cells. Efficacy depends on the ability to kill specific cancer cell types without affecting normal body cells. Studies on the effects of certain Ayurvedic herbal preparations for possible cytotoxic activity revealed that these herbal preparations did not kill the cancer cells but transformed them into normal healthy cells.⁽⁵⁾ These drugs, therefore, have a different mechanism of action, Classical testing methods would have missed this important anti-cancer activity.

I wish to pose a philosophical question. Is medical science one universal and uniquely expressed (western) paradigm – a biomedical paradigm? If it is possible to conceive of alternative methodologies, theories and practices in other domains such as music, logic, linguistics, art and politics, is it not possible to consider possibilities of alternative methodologies in medical science, knowing that doctors practice medicine within a bio-psycho-social paradigm?

The guiding principles by which knowledge is built up in the biomedical paradigm are those of the scientific method where hypotheses are clearly stated, then tested and accepted or rejected as truth "until further notice" or "within the stated confidence limits" using only experimental or quasi-experimental designs – a deductive approach to problem solving.

Is it possible for research scientists to examine other methodologies, for example, using experiential methods – an inductive approach, to evaluate traditional herbal remedies?

There is an enormous amount of research on medicinal plants in research institutes in developing countries and the transnational drug industry.

Based on the WHO definition of herbal remedies and the herbal remedies used by practitioners of the traditional system, I wish to pose the following questions:

The Indian Council of Medical Research has taken the plant *Pterocarpus marsupium* from its use in folklore and Ayurvedic medicine to Phase III clinical evaluation for the treatment of diabetes mellitus using well accepted pharmacological principles.⁽⁶⁾ It was handed over to the industry for

¹¹ Sheeha, M P and Atherton, D J 1992. A controlled Trial of Traditional Chinese medicinal Plants in Widespread Non-Exudative Atopic Eczema, British Journal of Dermatology, 126:179-184.

⁵ Bodeker, G.1994. "Traditional Health Knowledge & Public Policy": Nature and Resources, Vol 30, No 2; 5-16.

⁶ Chaudhury R R (2001) Antidiabetic effect of Vijayasar *Pterocarpus marsirpium*.

pharmaceutical development and marketing. This product will be marketed to practitioners of modern medicine. Table 4 lists some examples of modern drugs derived from plants that have been used in the traditional systems of medicine by ancient people around the world.

Table 4. Drugs from ethnotherapeutic field

Drugs	Ethnotherapeutic information
Morphine	Opium used by ancient Egyptians and Sumarians
Atropine	Used by Babylonians
Ephedrine	Used by the Chinese for respiratory ailment (2700 BC)
Quinine	Used by Peruvians for fever
Emetine	Used by Brazilians and South Americans for dysentery and to induce vomiting
Digoxin	Used in England in the 17th century for heart illness
Tubocurarine	Used as arrow poison by Red Indians
Reserpine	Rauwolfia serpentina used as "Folklore" remedy for mental diseases in Bihar (north India)
Artemisin	Used in ancient Chinese medicine for fever

- Modified for Table 1 in reference: Suhk Deo, Source: Gaitonde B 8 "Research, drug development and manufacture of herbal drugs" in Traditional medicines in Asia, opcit.

The question I wish to pose is as follows: "Will this type of research and development to isolate therapeutically active chemical ingredients achieve the objectives of this conference which is to promote the continuous development of traditional medicinal in the region to maximize its contribution in preserving and improving public health?"

Let me make it clear that R & D to isolate therapeutically active ingredients from medicinal plants is of critical importance. There is no doubt about it.

But what I wish for you'll to discuss is the need for research to evaluate the safety and efficacy of the herbal remedies used by practitioners of the traditional systems of medicine. For example table gives a 5 list of Ayurvedic remedies for some common ailments.

Table 5 Treatment of Common Diseases

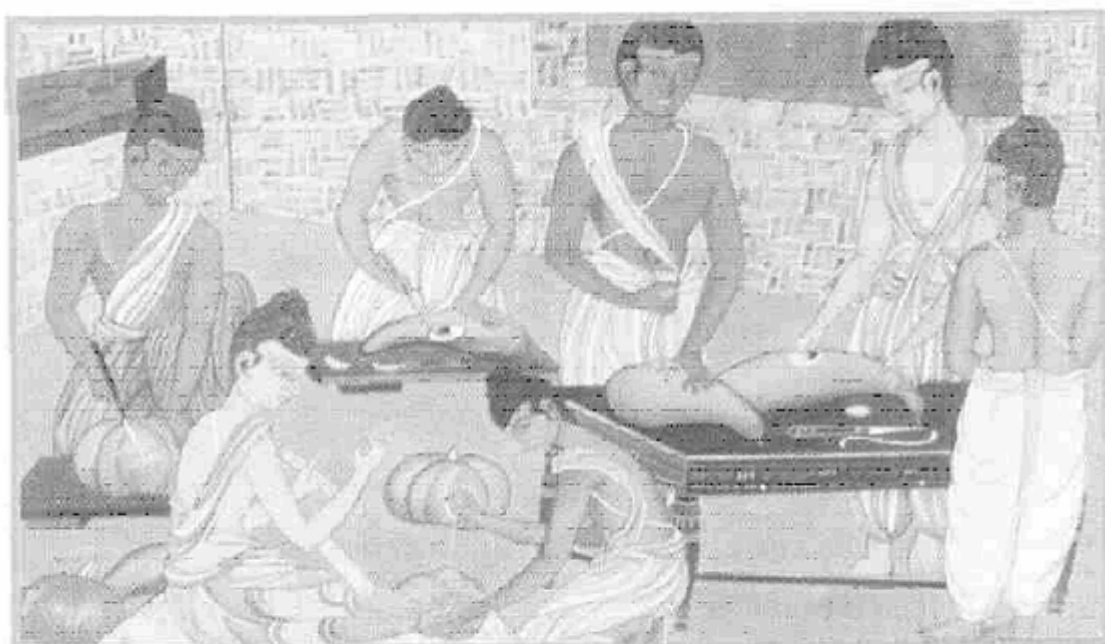
To deal with various common diseases at the primary health care level, many time-tested standard Ayurvedic formulations are highly effective.

Common Diseases	Treatment	Common Diseases	Treatment
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Common Cold	Laxmivilas rasa and Godanti Bhasma	Bacillary Dysentery	Sanjivani and Shankhodar
Fever	Tribhuvarikirti rasa, Godanti Bhasma and Sudarshan Ghanvati	Piles	Arshakuthar rasa
Hyper Acidity and Duodenal Ulcer	Sutshekhar rasa, Shankh Bhasma	Hepatitis	Arogyavardhani rasa Liver Diseases
Cough	Sitopaladi Khadiradvati	Dysfunctional Uterine Bleeding	Pushyanug
Gastro-intestinal problems	Shankhvati	Urinary Tract infection	Chandraprabha vati
Diarrhoea	Jatiphaladi, Karpura rasa	Arthritic Condition	Yograj guggulu and Rasnadi kvath
Diarrhoea and Amoebic Dysentery	Kutajghanavati	Gout	Kaishore guggulu
		Bronchial Asthma	Shvasa kuthar rasa
		Various Eye Diseases	Saptamrata lauha and Mahatriphalaghrita

Source: Kurup P N V. "Ayurveda" in Traditional Medicine in Asia, pal.

Is there a need to develop appropriate methods for clinical evaluation of traditional herbal medicines: methods and criteria not to be limited to the methods and concepts of modern biomedical science.



Pupils practising surgical procedures on vegetables in ancient India

comparison group.

The next issue we shall consider is: **Preserving and safeguarding Biodiversity, sustainability and traditional knowledges.**

In order to preserve and safeguard biodiversity, sustainability and traditional knowledge of medicinal plants, we need to examine intellectual property rights (IPRs) and the TRIPS Agreement.

An Intellectual Property (IP) is a creation of the Mind. Examples: artistic and literary works inventions, trade marks.

For protecting Herbal Medicines we need to focus on inventions. An invention is a process or a product which is new, useful and capable of manufacture. A patent is an intellectual property right (IPR) given for an invention by a government for a limited period of time.

For an invention to be patentable, it has to meet the following criteria:

- Novelty
- Inventiveness or inventive step
- Industrial applicability

Can herbal medicines be patented?

- Herbal medicines have been in use for centuries.
- Knowledge of their preparation is well known and documented.
- Neither the product nor the processes are new.
- Therefore herbal medicines that are in use cannot be patented.

But in March 1995, a United States patent on "Use of Turmeric in wound healing" was granted to the University of Mississippi Medical Centre. In 2000, a patent was granted to WR Grace Company and the US Department of Agriculture on Neem.

Under the US Law, Novelty is destroyed if an invention has been disclosed:

- Through publication; or
- Through use in US

Use of a herbal medicine outside the US does not destroy novelty. The US government justification is: if information is not written down, that information is completely inaccessible to patent examiners as prior art when they examine patent applications. It is possible, therefore, for a patent to be issued claiming as an invention technology that is only known to a particular indigenous community.

The patent was revoked when references to prior art was presented by CSIR which requested re-examination. A re-examination request for the patent on Basmati rice lines and grains granted by the US was also made by CSIR.

- Patent applications should be written in legal and scientific language. This requires services of very expensive patent lawyers. Costs of filing a patent are high.
- Protection against infringement. Legal action to defend a patent is very

expensive.

- An infringing company with considerable financial resources and access to eminent patent lawyers may well succeed in convincing the court that its product, or process or use are sufficiently different from the original to constitute an invention of its own or at least not to constitute an infringement.

The ongoing national, regional and international debates and discussions on IPR and herbal medicines are, therefore, not to explore possibilities for providing patent protection to herbal medicines but to:

- Protect traditional knowledge Prevent bio piracy; and
- Conserve genetic resources, medicinal plants and biodiversity.

A large number of patents have been granted on genetic resources and traditional knowledge obtained from developing countries without the consent of the possessors of the resources and knowledge.

- The TRIPS Agreement which is designed to protect IPRs is silent about the bio piracy of traditional knowledge and medicinal plants
- TRIPS does not find out from where the patent applicant obtained his knowledge.
- TRIPS allows countries to allow patenting of micro-organisms and micro-biological processes.

These two factors and together with the loose interpretation of "inventiveness" in national patent offices allow the patenting of traditional knowledge and genetic resources or bio piracy.

If a two percent royalty were levied on genetic resources, the North would owe South more than US\$ 5 billion in royalties for medicinal plants

Uncontrolled and unregulated commercial collection of genetic resources and harvesting and processing of medicinal plants have led to the near extinction of some very valuable medicinal plants.

Protecting traditional knowledge conservation of biodiversity, genetic resources and medicinal plants has therefore, become a global emergency. In response to this crisis, a number of inter governmental and international agencies have set in motion a series of initiatives for protection of traditional knowledge and conservation of genetic resources, bio diversity and medicinal plants.

International Initiatives

- Convention on International Trade on Endangered Species (CITES) 1975
- The Chiang Mai Declaration 1988
- 3, The Declaration of Belem, Brazil, 1988
- The Arusha Declaration, 1990
- The Convention on Biological Diversity 1992
- First World Convention on Medicinal and Aromatic Plants for Human Welfare 1992
- The 7th Asian Symposium on Medicinal Plants, Spices and other National Products, 1992

- African Ministerial Conference on Environment, 1994
- Intergovernmental Committee on Intellectual Property, Traditional Knowledge and Folklore (The WIPO Committee 2000)

The objectives of protecting Traditional Knowledge (TK) include the following:

- Prevent misappropriation of TK (bio-piracy);
- Preservation of traditional practices and cultures;
- Promotion of TK and its importance in R&D of traditional medicines;
- Conservation of medicinal plants, genetic resources and biodiversities; and
- Fair and equitable distribution of the benefits derived from technologies and innovations based on TK.

At present there is no consensus on what would be the most appropriate way of protecting TK to achieve the above objectives. TK can be protected within and outside the IPR's system. IPR's are seen as one possible mean to protect TK. There are strong supporters and severe critics of extending IPRs to protect TK.

In view of the lack of consensus, it may be premature to initiate discussions towards development of International standards in the framework of the World Trade Organization (WTO). The immediate priority should be the development of global rules to prevent the misappropriation of TK and use these as guidelines to develop national laws to prevent bio piracy.

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